DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug
Administration
Rockville MD 20857

NDA 20-998/S-008

G.D.Searle & Co.
Attention: Winifred M. Begley, Senior Director
Worldwide Regulatory Affairs
4901 Searle Parkway
Skokie, IL 60077

Dear Ms. Begley:

Please refer to your supplemental new drug application dated April 25, 2000, received April 26, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Celebrex (celecoxib capsules) 100 mg, 200 mg.

This supplemental new drug application provides labeling revisions to the Precautions sections, Pregnancy subsection in response to the FDA letter dated February 23, 2000.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted April 25, 2000).

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-998/S-008." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under

21 CFR 314.80 and 314.81.

If you have any questions, call Leslie Vaccari, Chief, Project Management Staff, at (301) 827-2538.

Sincerely,

Jonca C. Bull, M.D.
Deputy Director
Office of Drug Evaluation V
Center for Drug Evaluation and Research